

Exhibit M

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MITSUBISHI TANABE PHARMA
CORPORATION, JANSSEN
PHARMACEUTICALS, INC., JANSSEN
PHARMACEUTICA NV, JANSSEN
RESEARCH AND DEVELOPMENT, LLC,
and CILAG GMBH INTERNATIONAL,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA)
INC.,

Defendants.

**Civil Action No. 17-5005 (PGS)(DEA)
Civil Action No. 17-5135 (PGS)(DEA)
Civil Action No. 17-5278 (PGS)(DEA)
Civil Action No. 17-5302 (PGS)(DEA)
Civil Action No. 17-7342 (PGS)(DEA)
Civil Action No. 17-13130 (PGS)(DEA)
Civil Action No. 18-292 (PGS)(DEA)
(consolidated)**

**HIGHLY CONFIDENTIAL –
ATTORNEY EYES ONLY**

**PLAINTIFFS' DISCLOSURE OF INFRINGEMENT CONTENTIONS
OF THE ASSERTED CLAIMS**

Pursuant to Local Patent Rules 3.1, 3.2, and 3.6(g)-(h) of the United States District Court for the District of New Jersey and this Court's Scheduling Order dated March 1, 2018 (D.I. 40), Plaintiffs Mitsubishi Tanabe Pharma Corp. ("MTPC"), Janssen Pharmaceuticals, Inc. ("JPI"), Janssen Pharmaceutica NV ("JNV"), Janssen Research and Development, LLC ("JRD"), and Cilag GmbH International ("Cilag") (collectively, "Plaintiffs") hereby serve their Infringement Contentions on Defendant Zydus Pharmaceuticals ("Zydus") concerning United States Patent Nos. 7,943,582 (the "'582 patent") and 8,513,202 (the "'202 patent") (collectively, the "Patents-in-Suit").

Plaintiffs have prepared these contentions based on information and discovery currently available to them. Fact discovery remains open and expert discovery has not yet begun in this case. Further, Plaintiffs' investigation into the infringement of the asserted claims of the Patents-in-Suit continues, especially since Zydus has not yet produced all discovery pertaining to Abbreviated New Drug Application ("ANDA") No. 210542 and No. 210541 (collectively, "Zydus's ANDAs"), which form the basis for this action, and fact depositions specific to the Patents-in-Suit have not yet begun. In addition, Zydus has not yet produced the complete Drug Master File(s) ("DMF") associated with its ANDA. Further, claim construction exchanges and briefing have not yet begun, and the Court has not yet construed the claims of the Patents-in-Suit in this litigation.

Plaintiffs therefore reserve all rights to modify or supplement these contentions where appropriate as discovery in this case progresses and after the Court construes the asserted claims. Plaintiffs further reserve the right to assert additional or alternative claims. In the event that a claim limitation is deemed to be missing under a literal infringement analysis, Plaintiffs also reserve the right to demonstrate the presence of a substantial equivalent of such limitation and to

pursue infringement under the doctrine of equivalents. Accordingly, Plaintiffs reserve the right to amend these contentions where appropriate, as discovery in this case continues and/or in light of Zydus's claim-construction contentions, any modification or clarification of Zydus's non-infringement and invalidity contentions, any additional non-infringement or invalidity contentions from Zydus, and/or the Court's claim constructions.

These contentions are made pursuant to Federal Rule of Evidence 502 and the Discovery Confidentiality Order entered in this case. To the extent that these contentions contain any information that may be protected from discovery under the attorney-client privilege, the work-product doctrine, the common-interest privilege, or any other applicable privilege or immunity, such disclosure is inadvertent and does not constitute a waiver of any such privilege or immunity.

The contentions set forth below are based solely on Plaintiffs' current knowledge and belief, as based on the information concerning Zydus's ANDA Products that is currently available to Plaintiffs given the limited discovery that has occurred to-date in this action.

As described herein, Zydus's ANDA Products infringe each of the asserted claims of the patents-in-suit, either literally or under the doctrine of equivalents.

I. IDENTIFICATION PURSUANT TO L. PAT. R. 3.2

Pursuant to L. Pat. R. 3.2(a), Plaintiffs are not aware of any documents evidencing discussions with, disclosure to, or other manner of providing to a third party, or sale or offer to sell, or any public use of, the claimed inventions prior to the dates of application for the patents-in-suit.

Pursuant to L. Pat. R. 3.2(b), Plaintiffs identify JSN-INVP-00000001-5800; MTPC-INVP-0000251-561 as documents evidencing the conception, reduction to practice, design, and

development of inventions claimed in the asserted patents, and which were created on or before the date of application for those patents.

Pursuant to L. Pat. R. 3.2(c), Plaintiffs identify JSN-INVP-00000023-5800 as containing documents comprising a copy of the file history for each asserted patent.

Pursuant to L. Pat. R. 3.2(d), Plaintiffs identify JSN-INVP-00005803-5822; MTPC-INVP-0000001-251 as containing documents evidencing Plaintiffs' ownership of the asserted patents.

Pursuant to L. Pat. R. 3.2(e), Plaintiffs identify JSN-INV-00037552-52822; JSN-INV-00021431-52178 as containing documents evidencing aspects or elements of the instrumentalities that Plaintiffs may rely upon as embodying the claimed inventions.

Pursuant to L. Pat. R. 3.2(f), Plaintiffs identify the documents cited in its contentions as documents upon which it intends to rely in support of its infringement contentions.

Plaintiffs reserve the right to supplement these identifications if they later become aware of any additional relevant evidence as discovery progresses. Plaintiffs further reserve the right to modify their contentions following the receipt of Zydus's ANDA Products and further discovery related to Zydus's ANDA Products.

II. DISCLOSURE OF ASSERTED CLAIMS AND INFRINGEMENT CONTENTIONS

A. Zydus's ANDA Products will infringe the asserted claims of United States Patent No. 7,943,582

Pursuant to Local Patent Rule 3.1(a), Plaintiffs refer to their February 20, 2018 disclosures pursuant to Local Patent Rule 3.6(b). Plaintiffs restate herein that they assert claims 1, 3-4, and 6-7 of the '582 patent. For the reasons stated below, Zydus's filing of Zydus's ANDAs constitutes infringement of the asserted claims under 35 U.S.C. § 271(e)(2)(A), and Zydus's activities in connection with the manufacture, use, sale, offer for sale, and/or

importation of the drug products that are the subjects of Zydus's ANDAs will constitute direct infringement under 35 U.S.C. § 271(a) and indirect infringement under 35 U.S.C. §§ 271(b) and (c) of the asserted claims.

Pursuant to Local Patent Rule 3.1(b), Plaintiffs specifically identify Zydus's 50 mg/500 mg; 50 mg/1000 mg; 150 mg/500 mg; and 150 mg/1000 mg ANDA Products (described in ANDA No. 210542) and Zydus's 100 mg and 300 mg ANDA Products (described in ANDA No. 210541) and their accompanying package inserts and product labeling, as well as the canagliflozin used to make Zydus's ANDA Products, as the "Accused Instrumentality." Zydus's ANDA Products and the canagliflozin used to make Zydus's ANDA Products contain each and every limitation of claims 1, 3-4, and 6-7 of the '582 patent literally or under the doctrine of equivalents, and thus infringe those asserted claims as set forth herein.

Pursuant to Local Patent Rule 3.1(c), Plaintiffs supply the following claim chart identifying specifically where each limitation of each asserted claim is found within the Accused Instrumentality. Plaintiffs reserve the right to modify and/or supplement the claim charts herein where appropriate as discovery progresses.

Pursuant to Local Patent Rule 3.1(d), Plaintiffs allege that, upon FDA approval of ANDA No. 210542 and ANDA No. 210541, the manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Products will constitute direct and/or indirect infringement of the asserted claims of the '582 patent as described in the claim chart below.

Pursuant to Local Patent Rule 3.1(e), Plaintiffs state that each limitation of each asserted claim of the '582 patent is present literally or under the doctrine of equivalents in the Accused Instrumentality. Plaintiffs reserve the right to modify and/or supplement the claim charts herein where appropriate as discovery progresses. In the event that a claim limitation is deemed to be

missing under a literal-infringement analysis, Plaintiffs reserve the right to demonstrate the presence of a substantial equivalent of such an element and to pursue infringement under the doctrine of equivalents.

Pursuant to Local Patent Rule 3.1(f), for the reasons provided in Plaintiffs' Responses to Invalidity Contentions, served contemporaneously herewith, Plaintiffs state that each asserted claim of the '582 patent is entitled a priority date that is no later than December 4, 2006. Plaintiffs reserve the right to supplement and/or amend this disclosure.

Pursuant to Local Patent Rule 3.1(g), Plaintiffs identify Plaintiffs' Invokana[®] and Invokamet[®] drug products as embodying the inventions claimed in claims 1, 3-4, and 6-7 of the '582 patent.

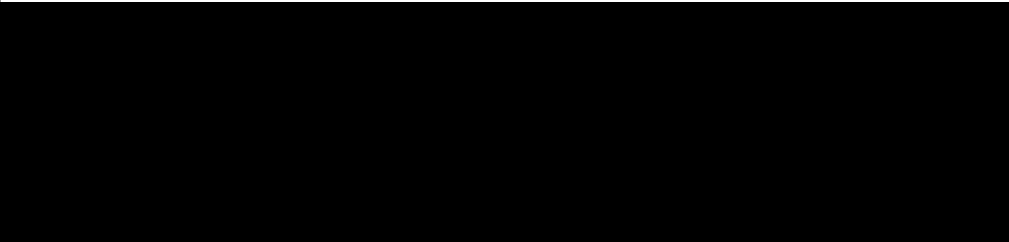
Pursuant to Local Patent Rule 3.1(h), Plaintiffs allege that Zydus seeks to willfully infringe the asserted claims of the '582 patent based on their knowledge of the existence of that patent and lack of any good faith non-infringement position.

Plaintiffs reserve the right to base their contentions on additional information in Zydus's production, deposition transcripts, interrogatory responses, responses to requests to admit, and/or any other pleadings, as well as expert testing and/or testimony. In particular, Plaintiffs reserve the right to supplement these contentions if they discover any additional evidence regarding infringement.

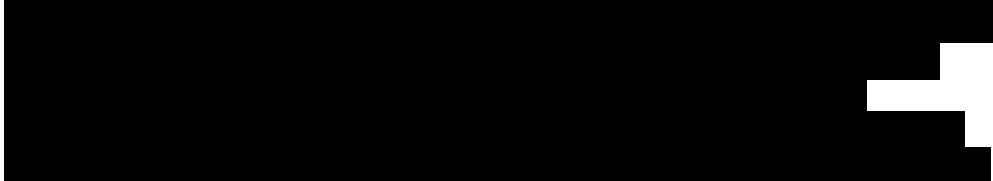
Plaintiffs contend that testing of Zydus's ANDA Products and the canagliflozin used to make Zydus's ANDA Products, as well as potential testimony from Zydus and others, will show that Zydus's ANDA Products meet certain limitations related to the canagliflozin of the asserted claims of the '582 patent. Plaintiffs disagree with Zydus's characterizations of the documents Zydus cites as alleged support of its non-infringement contention relating to the '582 patent.

'582 PATENT	Zydus's ANDA Product
<p>1. A crystalline form of 1-(β-D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate.</p>	<p>1. Zydus's ANDA Products will literally meet this limitation. This is supported by Zydus's document production, and may be further supported by additional fact discovery that has not yet occurred, and/or by evidence obtained and/or generated as part of expert discovery. <i>See, e.g.</i>, ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00002225-250; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00024022-024; ZYDUS-INVOKA2_0024421-024; ZYDUS-INVOKA 00001884-894; ZYDUS-INVOKA2_0001884-894; ZYDUS-INVOKA 00001578-579; ZYDUS-INVOKA2 00001578-579 ; ZYDUS-INVOKA 00002006-014; ZYDUS-INVOKA 00005326-5334; ZYDUS-INVOKA 00005335-339; ZYDUS-INVOKA 00024084-092; ZYDUS-INVOKA 00005340-373; ZYDUS-INVOKA 00001436; ZYDUS-INVOKA 00024093-126; ZYDUS-INVOKA2_0024193; ZYDUS-INVOKA 00001931-941; ZYDUS-INVOKA</p>

'582 PATENT	Zydus's ANDA Product
	<p>00024048-054; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678; Notice of Paragraph IV Certification from Zydus Pharmaceuticals (USA) Inc. against Invokana dated June 6, 2018; Notice of Paragraph IV Certification from Zydus Pharmaceuticals (USA) Inc. against Invokamet dated June 5, 2017.</p> <p>Zydus's DMF # 029827, including the method of manufacturing disclosed therein, will show that Zydus's ANDA Products contain a crystalline form of canagliflozin hemihydrate. ZYDUS-INVOKA 00000021-52095; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00002225-250; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA2_0002290-722; ZYDUS-INVOKA 00024341-557; ZYDUS-</p>


'582 PATENT	Zydus's ANDA Product
	<p>INVOKA2_0024740-956; ZYDUS-INVOKA 00002723-762; ZYDUS-INVOKA2_0002723-762 ; ZYDUS-INVOKA 00024558-580; ZYDUS-INVOKA2_0024957-979 ; ZYDUS-INVOKA 00001636-646; ZYDUS-INVOKA 00023774-784; ZYDUS-INVOKA2_0024173-183; ZYDUS-INVOKA2_0001420-426; ZYDUS-INVOKA_0001420-426; ZYDUS-INVOKA2_0024170-172 ; ZYDUS-INVOKA2_0001633-635; ZYDUS-INVOKA 00005340-373; ZYDUS-INVOKA 00001436; ZYDUS-INVOKA 00024093-126; ZYDUS-INVOKA2_0024193; ZYDUS-INVOKA 00001931-941; ZYDUS-INVOKA 00024048-054.</p>  <p>Plaintiffs disagree with Zydus's contention that "crystalline form" is indefinite, for at least the reasons set forth in Plaintiffs' responses to invalidity contentions.</p> <p>Zydus's ANDA Products literally infringe this claim.</p>
<p>3. A crystalline form of 1-(β-D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate of claim 1, having substantially the same X-ray diffraction pattern as set out in FIG. 1.</p>	<p>3. See claim 1. Zydus's ANDA Products will literally meet this limitation. This is supported by Zydus's document production, and may be further supported by additional fact discovery that has not yet occurred, and/or by evidence obtained and/or generated as part of expert discovery. <i>See, e.g.</i>, ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344;</p>

'582 PATENT	Zydus's ANDA Product
	<p>ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2_00000167-168; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678 ; Notice of Paragraph IV Certification from Zydus Pharmaceuticals (USA) Inc. against Invokana dated June 6, 2018; Notice of Paragraph IV Certification from Zydus Pharmaceuticals (USA) Inc. against Invokamet dated June 5, 2017.</p> <p>Zydus's DMF # 029867, including the method of manufacturing disclosed therein, will show that Zydus's ANDA Products contain canagliflozin with an X-ray diffraction pattern corresponding to the representative X-ray diffraction pattern depicted in FIG. 1. ZYDUS-INVOKA 00000021-52095; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA</p>

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	<p>00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168 ; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA2_0002290-722; ZYDUS-INVOKA 00024341-557; ZYDUS-INVOKA2_0024740-956; ZYDUS-INVOKA 00002723-762; ZYDUS-INVOKA2_0002723-762; ZYDUS-INVOKA 00024558-580; ZYDUS-INVOKA2_0024957-979; ZYDUS-INVOKA 00001636-646; ZYDUS-INVOKA 00023774-784; ZYDUS-INVOKA2_0024173-183; ZYDUS-INVOKA2_0001420-426; ZYDUS-INVOKA_0001420-426; ZYDUS-INVOKA2_0024170-172; ZYDUS-INVOKA2_0001633-635; ZYDUS-INVOKA 00005340-373; ZYDUS-INVOKA 00001436; ZYDUS-INVOKA 00024093-126; ZYDUS-INVOKA2_0024193; ZYDUS-INVOKA 00001931-941; ZYDUS-INVOKA 00024048-054.</p> 

'582 PATENT	Zydus's ANDA Product
	<div data-bbox="955 256 1934 375" style="background-color: black; height: 73px; width: 466px;"></div> <p>Plaintiffs disagree with Zydus's contentions that "crystalline form" and "substantially the same" are indefinite, for at least the reasons set forth in Plaintiffs' responses to invalidity contentions.</p> <p>Zydus's ANDA Products literally infringe this claim.</p>
<p>4. A crystalline form of 1-(β-D-glucopyranosyl)-4-methyl-3[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate of claim 1, having substantially the same IR spectrum, as set out in FIG. 2.</p>	<p>4. See claim 1. Zydus's ANDA Products will literally meet this limitation. This is supported by Zydus's document production, and may be further supported by additional fact discovery that has not yet occurred, and/or by evidence obtained and/or generated as part of expert discovery. <i>See, e.g.</i>, ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-</p>

'582 PATENT	Zydus's ANDA Product
	<p>INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p> <p>Zydus's DMF # 029867, including the method of manufacturing disclosed therein, will show that Zydus's ANDA Products contain canagliflozin with an infrared spectrum corresponding to the representative infrared spectrum depicted in FIG. 2. ZYDUS-INVOKA 00000021-52095; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA2_0002290-722; ZYDUS-</p>

'582 PATENT	Zydus's ANDA Product
	<p>INVOKA 00024341-557; ZYDUS-INVOKA2_0024740-956; ZYDUS-INVOKA 00024022-024; ZYDUS-INVOKA2_0024421-024; ZYDUS-INVOKA 00001884-894; ZYDUS-INVOKA2_0001884-894; ZYDUS-INVOKA 00001578-579; ZYDUS-INVOKA2 00001578-579 ; ZYDUS-INVOKA 00002006-014; ZYDUS-INVOKA 00005326-5334; ZYDUS-INVOKA 00005335-339; ZYDUS-INVOKA 00024084-092.</p>  <p>Plaintiffs disagree with Zydus's contentions that "crystalline form" and "substantially the same" are indefinite, for at least the reasons set forth in Plaintiffs' responses to invalidity contentions.</p> <p>Zydus's ANDA Products literally infringe this claim.</p>
<p>6. A pharmaceutical composition comprising an effective amount of a crystalline form of 1-(β-D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate of claim 1 and a pharmaceutically acceptable carrier.</p>	<p>6. See claim 1. Zydus's ANDA Products will literally meet this limitation. This is supported by Zydus's document production, and may be further supported by additional fact discovery that has not yet occurred, and/or by evidence obtained and/or generated as part of expert discovery. <i>See, e.g.</i>, ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-</p>

'582 PATENT	Zydus's ANDA Product
	<p>INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.,</i> ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678 .</p> <p>Zydus's ANDA Products are a pharmaceutical composition comprising an effective amount of a crystalline form of canagliflozin hemihydrate and a pharmaceutically acceptable excipient or carrier. ZYDUS-INVOKA 00000021-52095; <i>see also, e.g.,</i> ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-</p>

'582 PATENT	Zydus's ANDA Product
	<p>INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00000502-729; ZYDUS-INVOKA 00000730-962; ZYDUS-INVOKA 00023333-477; ZYDUS-INVOKA2_0002290-722; ZYDUS-INVOKA 00024341-557; ZYDUS-INVOKA2_0024740-956; ZYDUS-INVOKA 00024075-080; ZYDUS-INVOKA 00026058-065; ZYDUS-INVOKA2_0024474-479; ZYDUS-INVOKA2_0026457-464; ZYDUS-INVOKA 00001607-612; ZYDUS-INVOKA 00001997-2002; ZYDUS-INVOKA 00005313-321; ZYDUS-INVOKA2_0001607-612; ZYDUS-INVOKA2_0005313-321; ZYDUS-INVOKA 00002723-762; ZYDUS-INVOKA2_0002723-762; ZYDUS-INVOKA 00024558-580; ZYDUS-INVOKA2_0024957-979; ZYDUS-INVOKA 00001636-646; ZYDUS-INVOKA 00023774-784; ZYDUS-INVOKA2_0024173-183; ZYDUS-INVOKA2_0001420-426; ZYDUS-INVOKA_0001420-426; ZYDUS-INVOKA2_0024170-172; ZYDUS-INVOKA2_0001633-635; ZYDUS-INVOKA 00005340-373; ZYDUS-INVOKA 00001436; ZYDUS-INVOKA 00024093-126; ZYDUS-INVOKA2_0024193.</p> <p>Zydus's DMF # 029867 will show that Zydus's ANDA Products contain an effective amount of a crystalline form of canagliflozin hemihydrate described in claim 1.</p> <p>Zydus's ANDA Products are in the form of tablets, which are pharmaceutically acceptable carriers. <i>See, e.g.,</i> ZYDUS-INVOKA</p>

'582 PATENT	Zydus's ANDA Product
	<p>00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.,</i> ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00002225-250; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; '582 Patent at 3:62-67 ("Suitable pharmaceutical preparations for oral administration include, for example, solid preparations such as tablets . . ."); <i>see also, e.g.,</i> ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p> <p>Zydus's assertion that "Zydus's ANDA Products do not contain an 'effective amount' of a crystalline hemihydrate form of [canagliflozin] hemihydrate" is inapposite. Testing of Zydus's ANDA Products and the canagliflozin used</p>

'582 PATENT	Zydus's ANDA Product
	<p>to make Zydus's ANDA Products, as well as potential testimony from Zydus and potential third parties, will show that Zydus's ANDA Products are pharmaceutical compositions comprising an effective amount of a crystalline form of canagliflozin hemihydrate described in claim 1 and a pharmaceutically acceptable carrier.</p> <p>Plaintiffs disagree with Zydus's contention that "crystalline form" is indefinite, for at least the reasons set forth in Plaintiffs' responses to invalidity contentions.</p> <p>Zydus's ANDA Products literally infringe this claim.</p>
<p>7. A method for treatment or delaying the progression or onset of diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, or hypertension, which comprises administering a therapeutically effective amount of a crystalline form of 1-(β-D-glucopyranosyl)-4-methyl-3[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate of claim 1 to a subject in need thereof.</p>	<p>7. See claim 1. The use of Zydus's ANDA Products (e.g., by doctors, other healthcare professionals, or patients) in accordance with Zydus's proposed package insert will literally meet each and every element of claim 7. . This is supported by Zydus's document production, and may be further supported by additional fact discovery that has not yet occurred, and/or by evidence obtained and/or generated as part of expert discovery. <i>See, e.g.</i>, ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2_00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-</p>

'582 PATENT	Zydus's ANDA Product
	<p>INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.,</i> ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p> <p>The use of Zydus's ANDA Products (e.g. by doctors, other healthcare professionals, or patients) according to the instructions set forth in Zydus's package insert (either the currently proposed version or any version that copies the Invokana[®] or Invokamet[®] package inserts) will constitute direct infringement of claim 7. Zydus will induce or contribute to that direct infringement by instructing and encouraging others to use Zydus's ANDA Products according to Zydus's publicly available product labeling, including, but not limited to, the package insert for Zydus's ANDA Products. Zydus's ANDA Products are specifically adapted for use in connection with the claimed methods. There are no substantial non-infringing uses of Zydus's ANDA Products.</p> <p>Zydus's ANDA Products are a pharmaceutical composition containing an effective amount of a crystalline form of canagliflozin hemihydrate and a pharmaceutically acceptable excipient or carrier.</p> <p>Zydus's DMF # 029867, including the method of manufacturing disclosed therein, will show that Zydus's ANDA Products contain a therapeutically effective amount of a crystalline form of canagliflozin hemihydrate described</p>

'582 PATENT	Zydus's ANDA Product
	<p>in claim 1. ZYDUS-INVOKA 00000021-52095; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00002225-250; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00000502-729; ZYDUS-INVOKA 00000730-962; ZYDUS-INVOKA 00023333-477; ZYDUS-INVOKA2_0002290-722; ZYDUS-INVOKA 00024341-557; ZYDUS-INVOKA2_0024740-956; ZYDUS-INVOKA 00024075-080; ZYDUS-INVOKA 00026058-065; ZYDUS-INVOKA2_0024474-479; ZYDUS-INVOKA2_0026457-464; ZYDUS-INVOKA 00001607-612; ZYDUS-INVOKA 00001997-2002; ZYDUS-INVOKA 00005313-321; ZYDUS-INVOKA2_0001607-612; ZYDUS-INVOKA2_0005313-321; ZYDUS-INVOKA 00002723-762; ZYDUS-INVOKA2_0002723-762; ZYDUS-INVOKA 00024558-580; ZYDUS-INVOKA2_0024957-979; ZYDUS-INVOKA 00001636-646; ZYDUS-INVOKA 00023774-784; ZYDUS-INVOKA2_0024173-183; ZYDUS-</p>

'582 PATENT	Zydus's ANDA Product
	<p>INVOKA2_0001420-426; ZYDUS-INVOKA_0001420-426; ZYDUS-INVOKA2_0024170-172; ZYDUS-INVOKA2_0001633-635; ZYDUS-INVOKA 00005340-373; ZYDUS-INVOKA 00001436; ZYDUS-INVOKA 00024093-126; ZYDUS-INVOKA2_0024193.</p> <p>Zydus's assertions that its "ANDA Products do not contain a 'therapeutically effective amount' of a crystalline hemihydrate form of [canagliflozin] hemihydrate" and "will not include a package insert, label, or other information directing a subject who needs 'treatment or delaying the progression or onset of diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, or hypertension' to administer or be administered a therapeutically effective amount of a crystalline form of [canagliflozin] hemihydrate" are inapposite. Testing of Zydus's ANDA Products and the canagliflozin used to make Zydus's ANDA Products, as well as potential testimony from Zydus and potential third parties, will show that Zydus's ANDA Products contain a therapeutically effective amount of a crystalline form of canagliflozin hemihydrate described in claim 1.</p> <p>Zydus's ANDA Products will treat or delay the progression or onset of diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, or hypertension. <i>See, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA</p>

'582 PATENT	Zydus's ANDA Product
	<p>00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; ZYDUS-INVOKA 00000502-729; ZYDUS-INVOKA 00000730-962; ZYDUS-INVOKA 00023333-477; ZYDUS-INVOKA 00035285-351; ZYDUS-INVOKA2_0035684-750; ZYDUS-INVOKA 00013423-514; ZYDUS-INVOKA2_0013423-514; ZYDUS-INVOKA2_0016395-489; ZYDUS-INVOKA 00016395-489; <i>see also, e.g.,</i> ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678 .</p> <p>Zydus's ANDA Products will be administered to patients having diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, or hypertension. <i>See, e.g.,</i> ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA</p>

'582 PATENT	Zydus's ANDA Product
	<p>00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; ZYDUS-INVOKA 00000502-729; ZYDUS-INVOKA 00000730-962; ZYDUS-INVOKA 00023333-477; <i>see also, e.g.,</i> ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p> <p>Zydus's ANDA, including the prescribing insert and labeling information, instructs and encourages the administration of a therapeutically effective amount of Zydus's ANDA Products, which contain a crystalline form of canagliflozin hemihydrate, to a subject in need thereof as a method of delaying the progression or onset of diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty</p>

'582 PATENT	Zydus's ANDA Product
	<p>acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, or hypertension. <i>See, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p> <p>Plaintiffs disagree with Zydus's contention that "crystalline form" is indefinite, for at least the reasons set forth in Plaintiffs' responses to invalidity contentions.</p>

'582 PATENT	Zydus's ANDA Product
	Zydus's ANDA Products literally infringe this claim.

B. Zydus's ANDA Products will infringe the asserted claims of United States Patent No. 8,513,202

Pursuant to Local Patent Rule 3.1(a), Plaintiffs refer to their February 20, 2018 disclosures pursuant to Local Patent Rule 3.6(b). Plaintiffs restate herein that they assert claims 1 and 3-5 of the '202 patent. For the reasons stated below, Zydus's filing of Zydus's ANDAs constitutes infringement of the asserted claims under 35 U.S.C. § 271(e)(2)(A), and Zydus's activities in connection with the manufacture, use, sale, offer for sale, and/or importation of the drug products that are the subjects of Zydus's ANDAs will constitute direct infringement under 35 U.S.C. § 271(a) and indirect infringement under 35 U.S.C. §§ 271(b) and (c) of the asserted claims.

[REDACTED]

Pursuant to Local Patent Rule 3.1(c), Plaintiffs supply the following claim chart identifying specifically where each limitation of each asserted claim is found within the Accused Instrumentality. Plaintiffs reserve the right to modify and/or supplement the claim charts herein where appropriate as discovery progresses.

Pursuant to Local Patent Rule 3.1(d), Plaintiffs allege that, upon FDA approval of ANDA Nos. 210542 and 210541, the manufacture, use, sale, offer for sale, and/or importation of

Zydus's ANDA Products will constitute direct and/or indirect infringement of the asserted claims of the '202 patent as described in the claim chart below.

Pursuant to Local Patent Rule 3.1(e), Plaintiffs state that each limitation of each asserted claim of the '202 patent is present literally or under the doctrine of equivalents in the Accused Instrumentality. Plaintiffs reserve the right to modify and/or supplement the claim charts herein where appropriate as discovery progresses. In the event that a claim limitation is deemed to be missing under a literal-infringement analysis, Plaintiffs reserve the right to demonstrate the presence of a substantial equivalent of such an element and to pursue infringement under the doctrine of equivalents.

Pursuant to Local Patent Rule 3.1(f), for the reasons provided in Plaintiffs' Responses to Invalidity Contentions, served contemporaneously herewith, Plaintiffs state that each asserted claim of the '202 patent is entitled a priority date that is no later than December 4, 2006. Plaintiffs reserve the right to supplement and/or amend this disclosure.

Pursuant to Local Patent Rule 3.1(g), Plaintiffs identify Plaintiffs' Invokana[®] and Invokamet[®] drug products as embodying the inventions claimed in claims 1 and 3-5 of the '202 patent.

Pursuant to Local Patent Rule 3.1(h), Plaintiffs allege that Zydus seeks to willfully infringe the asserted claims of the '202 patent based on its knowledge of the existence of that patent and lack of any good faith non-infringement position.


Plaintiffs reserve the right to base its contentions on additional information in Zydus's production, deposition transcripts, interrogatory responses, responses to requests to admit, and/or any other pleadings, as well as expert testing and/or testimony. In particular, Plaintiffs reserve

the right to supplement these contentions if it discovers any additional evidence regarding infringement.

Plaintiffs contend that testing of Zydus's ANDA Products and the canagliflozin used to make Zydus's ANDA Products, as well as potential testimony from Zydus and others, will show that Zydus's ANDA Products meet certain limitations related to the canagliflozin of the asserted claims of the '202 patent. Plaintiffs disagree with Zydus's characterization of the documents Zydus cites as alleged support of its non-infringement contentions relating to the '202 patent.

'202 PATENT	Zydus's ANDA Product
<p>1. A crystalline form of 1-(β-D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate having an infra-red spectrum in mineral oil comprising the following main peaks: 1626, 1600, 1549, and 1507 cm⁻¹.</p>	<p>1. Zydus's ANDA Products will literally meet this limitation. This is supported by Zydus's document production, and may be further supported by additional fact discovery that has not yet occurred, and/or by evidence obtained and/or generated as part of expert discovery. <i>See, e.g.</i>, ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; ZYDUS-INVOKA 00024022-024; ZYDUS-INVOKA2_0024421-024; ZYDUS-INVOKA 00001884-894; ZYDUS-INVOKA2_0001884-894; ZYDUS-INVOKA 00001578-579; ZYDUS-INVOKA2 00001578-579; ZYDUS-INVOKA 00002006-014; ZYDUS-INVOKA 00005326-5334; ZYDUS-INVOKA 00005335-339; ZYDUS-INVOKA 00024084-092; ZYDUS-INVOKA 00005340-373; ZYDUS-INVOKA 00001436; ZYDUS-INVOKA 00024093-126; ZYDUS-INVOKA2_0024193; ZYDUS-INVOKA 00001931-941; ZYDUS-INVOKA</p>

'202 PATENT	Zydus's ANDA Product
	<p>00024048-054; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678; Notice of Paragraph IV Certification from Zydus Pharmaceuticals (USA) Inc. against Invokana dated June 6, 2018; Notice of Paragraph IV Certification from Zydus Pharmaceuticals (USA) Inc. against Invokamet dated June 5, 2017.</p> <p>Zydus's DMF # 029867, including the method of manufacturing disclosed therein, will show that Zydus's ANDA Products contain canagliflozin with an infrared spectrum having main peaks at 1626, 1600, 1549, and 1507 cm⁻¹. ZYDUS-INVOKA 00000021-52095; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00000502-729; ZYDUS-</p>

'202 PATENT	Zydus's ANDA Product
	<p>INVOKA 00000730-962; ZYDUS-INVOKA 00023333-477; ZYDUS-INVOKA2_0002290-722; ZYDUS-INVOKA 00024341-557; ZYDUS-INVOKA2_0024740-956; ZYDUS-INVOKA 00024022-024; ZYDUS-INVOKA2_0024421-024; ZYDUS-INVOKA 00001884-894; ZYDUS-INVOKA2_0001884-894; ZYDUS-INVOKA 00001578-579; ZYDUS-INVOKA2 00001578-579; ZYDUS-INVOKA 00002006-014; ZYDUS-INVOKA 00005326-5334; ZYDUS-INVOKA 00005335-339; ZYDUS-INVOKA 00024084-092.</p>  <p>Plaintiffs disagree with Zydus's contention that "crystalline form" is indefinite, for at least the reasons set forth in Plaintiffs' responses to invalidity contentions.</p> <p>Zydus's ANDA Products literally infringe this claim.</p>
<p>3. A pharmaceutical composition comprising an effective amount of a crystalline form of 1-(β-D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-</p>	<p>3. See claim 1. Zydus's ANDA Products will literally meet this limitation. This is supported by Zydus's document production, and may be further supported by additional fact discovery that has not yet occurred, and/or by evidence obtained and/or generated as part of expert discovery. <i>See, e.g.,</i></p>

'202 PATENT	Zydus's ANDA Product
<p>thienylmethyl]benzene hemihydrate of claim 1 and a pharmaceutically acceptable carrier.</p>	<p>ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678 .</p> <p>Zydus's ANDA Products are a pharmaceutical composition containing an effective amount of a crystalline form of canagliflozin hemihydrate and a pharmaceutically acceptable excipient or carrier.</p> <p>Zydus's DMF # 029867, including the method of manufacturing disclosed therein, will show that Zydus's ANDA Products contain an effective amount of a crystalline form of canagliflozin hemihydrate described in claim 1.</p>

'202 PATENT	Zydus's ANDA Product
	<p>ZYDUS-INVOKA 00000021-52095; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00002225-250; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00000502-729; ZYDUS-INVOKA 00000730-962; ZYDUS-INVOKA 00023333-477; ZYDUS-INVOKA2_0002290-722; ZYDUS-INVOKA 00024341-557; ZYDUS-INVOKA2_0024740-956; ZYDUS-INVOKA 00024075-080; ZYDUS-INVOKA 00026058-065; ZYDUS-INVOKA2_0024474-479; ZYDUS-INVOKA2_0026457-464; ZYDUS-INVOKA 00001607-612; ZYDUS-INVOKA 00001997-2002; ZYDUS-INVOKA 00005313-321; ZYDUS-INVOKA2_0001607-612; ZYDUS-INVOKA2_0005313-321; ZYDUS-INVOKA 00002723-762; ZYDUS-INVOKA2_0002723-762; ZYDUS-INVOKA 00024558-580; ZYDUS-INVOKA2_0024957-979; ZYDUS-INVOKA 00001636-646; ZYDUS-INVOKA 00023774-784; ZYDUS-INVOKA2_0024173-183; ZYDUS-</p>

'202 PATENT	Zydus's ANDA Product
	<p>INVOKA2_0001420-426; ZYDUS-INVOKA_0001420-426; ZYDUS-INVOKA2_0024170-172; ZYDUS-INVOKA2_0001633-635; ZYDUS-INVOKA 00005340-373; ZYDUS-INVOKA 00001436; ZYDUS-INVOKA 00024093-126; ZYDUS-INVOKA2_0024193.</p> <p>Zydus's ANDA Products are in the form of tablets, which are pharmaceutically acceptable carriers. <i>See, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; '202 Patent at 4:5-9 ("Suitable pharmaceutical preparations for oral administration include, for example, solid preparations such as tablets . . ."); <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-</p>

'202 PATENT	Zydus's ANDA Product
	<p>INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p> <p>Testing of Zydus's ANDA Products and the canagliflozin used to make Zydus's ANDA Products, as well as potential testimony from Zydus and potential third parties, will show that Zydus's ANDA Products are pharmaceutical compositions comprising an effective amount of a crystalline form of canagliflozin hemihydrate described in claim 1 and a pharmaceutically acceptable carrier.</p> <p>Plaintiffs disagree with Zydus's contention that "crystalline form" is indefinite, for at least the reasons set forth in Plaintiffs' responses to invalidity contentions.</p> <p>Zydus's ANDA Products literally infringe this claim.</p>
<p>4. A method for treatment or delaying the progression or onset of diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, or hypertension, which comprises administering a therapeutically effective amount of a crystalline form of 1-(β-D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate of claim 1 to a subject in need thereof.</p>	<p>4. See Claim 1. The use of Zydus's ANDA Products in accordance with Zydus's proposed package insert will literally meet each and every element of claim 4. This is supported by Zydus's document production, and may be further supported by additional fact discovery that has not yet occurred, and/or by evidence obtained and/or generated as part of expert discovery. <i>See, e.g.</i>, ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-</p>

'202 PATENT	Zydus's ANDA Product
	<p>INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.,</i> ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p> <p>The use of Zydus's ANDA Products (e.g. by doctors, other healthcare professionals, or patients) according to the instructions set forth in Zydus's package insert (either the currently proposed version or any version that copies the Invokana[®] or Invokamet[®] package inserts) will constitute direct infringement of claim 4. Zydus will induce or contribute to that direct infringement by instructing and encouraging others to use Zydus's ANDA Products according to Zydus's publicly available product labeling, including, but not limited to, the package insert for Zydus's ANDA Products. Zydus's ANDA Products are specifically adapted for use in connection with the claimed methods. There are no substantial non-infringing uses of Zydus's ANDA Products.</p> <p>Zydus's ANDA Products are a pharmaceutical composition containing an effective amount of a crystalline form of canagliflozin hemihydrate and a pharmaceutically acceptable excipient or carrier.</p>

'202 PATENT	Zydus's ANDA Product
	<p>Zydus's DMF # 029867, including the method of manufacturing disclosed therein, will show that Zydus's ANDA Products contain a therapeutically effective amount of a crystalline form of canagliflozin hemihydrate described in claim 1. ZYDUS-INVOKA 00000021-52095; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2_00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00000502-729; ZYDUS-INVOKA 00000730-962; ZYDUS-INVOKA 00023333-477; ZYDUS-INVOKA2_0002290-722; ZYDUS-INVOKA 00024341-557; ZYDUS-INVOKA2_0024740-956; ZYDUS-INVOKA 00024075-080; ZYDUS-INVOKA 00026058-065; ZYDUS-INVOKA2_0024474-479; ZYDUS-INVOKA2_0026457-464; ZYDUS-INVOKA 00001607-612; ZYDUS-INVOKA 00001997-2002; ZYDUS-INVOKA 00005313-321; ZYDUS-INVOKA2_0001607-612; ZYDUS-INVOKA2_0005313-321; ZYDUS-INVOKA 00002723-762; ZYDUS-INVOKA2_0002723-762; ZYDUS-</p>

'202 PATENT	Zydus's ANDA Product
	<p>INVOKA 00024558-580; ZYDUS-INVOKA2_0024957-979; ZYDUS-INVOKA 00001636-646; ZYDUS-INVOKA 00023774-784; ZYDUS-INVOKA2_0024173-183; ZYDUS-INVOKA2_0001420-426; ZYDUS-INVOKA_0001420-426; ZYDUS-INVOKA2_0024170-172; ZYDUS-INVOKA2_0001633-635; ZYDUS-INVOKA 00005340-373; ZYDUS-INVOKA 00001436; ZYDUS-INVOKA 00024093-126; ZYDUS-INVOKA2_0024193.</p> <p>Zydus's assertions that its ANDA Products "do not contain a 'therapeutically effective amount' of a crystalline hemihydrate form of [canagliflozin] hemihydrate" and "will not include a package insert, label, or other information directing a subject who needs 'treatment or delaying the progression or onset of diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, or hypertension' which comprises administering a therapeutically effective amount of a crystalline form of [canagliflozin] hemihydrate of claim 1 to a subject in need thereof" are inapposite. Testing of Zydus's ANDA Products and the canagliflozin used to make Zydus's ANDA Products, as well as potential testimony from Zydus and potential third parties, will show that Zydus's ANDA Products contain a therapeutically effective amount of a crystalline form of canagliflozin hemihydrate described in claim 1.</p> <p>Zydus's ANDA Products will treat or delay the progression or onset of diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, or hypertension. ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA</p>

'202 PATENT	Zydus's ANDA Product
	<p>00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; ZYDUS-INVOKA 00000502-729; ZYDUS-INVOKA 00000730-962; ZYDUS-INVOKA 00023333-477; ZYDUS-INVOKA 00035285-351; ZYDUS-INVOKA2_0035684-750; ZYDUS-INVOKA 00013423-514; ZYDUS-INVOKA2_0013423-514; ZYDUS-INVOKA2_0016395-489; ZYDUS-INVOKA 00016395-489; <i>see also, e.g.,</i> ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p> <p>Zydus's ANDA Products will be administered to patients having diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic</p>

'202 PATENT	Zydus's ANDA Product
	<p>complications, atherosclerosis, or hypertension. <i>See, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; ZYDUS-INVOKA 00000502-729; ZYDUS-INVOKA 00000730-962; ZYDUS-INVOKA 00023333-477; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p> <p>Zydus's ANDA, including the prescribing insert and labeling information, instructs and encourages the administration of a therapeutically effective amount of Zydus's ANDA Products, which contain a crystalline form of canagliflozin hemihydrate, to a subject in need thereof as a method of delaying the progression or onset of diabetes mellitus, diabetic retinopathy,</p>

'202 PATENT	Zydus's ANDA Product
	<p>diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, or hypertension. <i>See, e.g.</i>, ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p>

'202 PATENT	Zydus's ANDA Product
	<p>Plaintiffs disagree with Zydus's contention that "crystalline form" is indefinite, for at least the reasons set forth in Plaintiffs' responses to invalidity contentions.</p> <p>Zydus's ANDA Products literally infringe this claim.</p>
<p>5. A method for inhibiting a sodium-dependent glucose transporter in a mammal in need thereof, comprising administering to said mammal a therapeutically effective amount of the crystalline form of hemihydrate of 1-(β-D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene of claim 1.</p>	<p>5. See Claim 1. The use of Zydus's ANDA Products (e.g., by doctors, other healthcare professionals, or patients) will literally meet this limitation. This is supported by Zydus's document production, and may be further supported by additional fact discovery that has not yet occurred, and/or by evidence obtained and/or generated as part of expert discovery. <i>See, e.g.</i>, ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-</p>

'202 PATENT	Zydus's ANDA Product
	<p>INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678 .</p> <p>The use of Zydus's ANDA Products (e.g. by doctors, other healthcare professionals, or patients) according to the instructions set forth in Zydus's package insert (either the currently proposed version or any version that copies the Invokana[®] or Invokamet[®] package inserts) will constitute direct infringement of claim 5. Zydus will induce or contribute to that direct infringement by instructing and encouraging others to use Zydus's ANDA Products according to Zydus's publicly available product labeling, including, but not limited to, the package insert for Zydus's ANDA Products. Zydus's ANDA Products are specifically adapted for use in connection with the claimed methods. There are no substantial non-infringing uses of Zydus's ANDA Products.</p> <p>Zydus's ANDA Products are a pharmaceutical composition containing a therapeutically effective amount of a crystalline form of canagliflozin hemihydrate and a pharmaceutically acceptable excipient or carrier.</p> <p>Zydus's DMF # 029867, including the method of manufacturing disclosed therein, will show that Zydus's ANDA Products contain a therapeutically effective amount of a crystalline form of canagliflozin hemihydrate described in claim 1. ZYDUS-INVOKA 00000021-52095; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-</p>

'202 PATENT	Zydus's ANDA Product
	<p>INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00000502-729; ZYDUS-INVOKA 00000730-962; ZYDUS-INVOKA 00023333-477; ZYDUS-INVOKA2_0002290-722; ZYDUS-INVOKA 00024341-557; ZYDUS-INVOKA2_0024740-956; ZYDUS-INVOKA 00024075-080; ZYDUS-INVOKA 00026058-065; ZYDUS-INVOKA2_0024474-479; ZYDUS-INVOKA2_0026457-464; ZYDUS-INVOKA 00001607-612; ZYDUS-INVOKA 00001997-2002; ZYDUS-INVOKA 00005313-321; ZYDUS-INVOKA2_0001607-612; ZYDUS-INVOKA2_0005313-321; ZYDUS-INVOKA 00002723-762; ZYDUS-INVOKA2_0002723-762; ZYDUS-INVOKA 00024558-580; ZYDUS-INVOKA2_0024957-979; ZYDUS-INVOKA 00001636-646; ZYDUS-INVOKA 00023774-784; ZYDUS-INVOKA2_0024173-183; ZYDUS-INVOKA2_0001420-426; ZYDUS-INVOKA 0001420-426; ZYDUS-INVOKA2_0024170-172; ZYDUS-INVOKA2_0001633-635; ZYDUS-INVOKA 00005340-373; ZYDUS-INVOKA 00001436; ZYDUS-INVOKA 00024093-126; ZYDUS-INVOKA2_0024193.</p>

'202 PATENT	Zydus's ANDA Product
	<p>Zydus's assertions that its ANDA Products "do not contain a 'therapeutically effective amount' of a crystalline hemihydrate form of [canagliflozin] hemihydrate" and "will not include a package insert, label, or other information directing a method for 'inhibiting a sodium-dependent glucose transporter in a mammal in need thereof, comprising administering to said mammal a therapeutically effective amount of the crystalline form of hemihydrate of [canagliflozin] of claim 1'" are inapposite. Testing of Zydus's ANDA Products and the canagliflozin used to make Zydus's ANDA Products, as well as potential testimony from Zydus and potential third parties, will show that Zydus's ANDA Products contain a therapeutically effective amount of a crystalline form of canagliflozin hemihydrate described in claim 1.</p> <p>Zydus's ANDA, including the prescribing insert and labeling information, instructs and encourages the administration of a therapeutically effective amount of Zydus's ANDA Products, which contain a crystalline form of canagliflozin hemihydrate, as a method for inhibiting a sodium-dependent glucose transporter in a mammal in need thereof. <i>See, e.g.</i>, ZYDUS-INVOKA 00000021-52095; ZYDUS-INVOKA 00000308-315; ZYDUS-INVOKA 00000316-323; ZYDUS-INVOKA 00000186-246; ZYDUS-INVOKA 00000247-307; ZYDUS-INVOKA 00000324-344; ZYDUS-INVOKA 00000368-369; ZYDUS-INVOKA 00000370-433; ZYDUS-INVOKA 00000179; ZYDUS-INVOKA 00000185; ZYDUS-INVOKA 00022981-3028; ZYDUS-INVOKA 00023077-081; ZYDUS-INVOKA2_0023481-485; ZYDUS-INVOKA2_0023476-480; ZYDUS-INVOKA 00022965-968; ZYDUS-INVOKA 00022969-970; ZYDUS-INVOKA 00022980; ZYDUS-INVOKA2_0023379; ZYDUS-INVOKA2_0023622-675; ZYDUS-INVOKA2_0023620-621; ZYDUS-INVOKA 00000167-168; ZYDUS-INVOKA2 00000167-168; ZYDUS-INVOKA 00000354-367; ZYDUS-INVOKA2_0023606-619; ZYDUS-INVOKA 00022946-947; ZYDUS-INVOKA2_0023345-346; ZYDUS-INVOKA 00000174-178; ZYDUS-INVOKA 00000180-184; ZYDUS-</p>

'202 PATENT	Zydus's ANDA Product
	<p>INVOKA 00022963-964; ZYDUS-INVOKA 00022971-972; ZYDUS-INVOKA 00022973-974; ZYDUS-INVOKA2_0023351-352; ZYDUS-INVOKA2_0023353-359; ZYDUS-INVOKA2_0023362-363; ZYDUS-INVOKA2_0023364-367; ZYDUS-INVOKA2_0023372-373; ZYDUS-INVOKA2_0023370-371; ZYDUS-INVOKA2_0023368-369; ZYDUS-INVOKA 00002225-250; <i>see also, e.g.</i>, ZYDUS-INVOKA 00000434; ZYDUS-INVOKA 00000493-496; ZYDUS-INVOKA 00000440-492; ZYDUS-INVOKA 00000435-439; ZYDUS-INVOKA2_0023676; ZYDUS-INVOKA2_0023724-726; ZYDUS-INVOKA2_0023679-723; ZYDUS-INVOKA2_0023677-678.</p> <p>Plaintiffs disagree with Zydus's contention that "crystalline form" is indefinite, for at least the reasons set forth in Plaintiffs' responses to invalidity contentions.</p> <p>Zydus's ANDA Products literally infringe this claim.</p>

Dated: June 29, 2018

By: 

Raymond N. Nimrod
Matthew A. Traupman
Melissa Baily
Catherine T. Mattes
QUINN EMANUEL URQUHART & SULLIVAN LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

Charles M. Lizza
William C. Baton
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs
Mitsubishi Tanabe Pharma Corp., Janssen
Pharmaceuticals, Inc., Janssen Pharmaceutica NV,
Janssen Research and Development, LLC, and
Cilag GmbH International